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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,211	11/02/2000	Stephen Donovan	17341DIV1	7309

7590 07/15/2003

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EXAMINER	
BUGAISKY, GABRIELE E	
ART UNIT	PAPER NUMBER
1653	8

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/706,211	DONOVAN, STEPHEN	
	Examiner	Art Unit	
	Gabriele E. BUGAISKY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The preliminary amendment is acknowledged. Claims 1-7 and 9-12 are currently pending. The requested amendment (9) to page 6, line 5 of the specification has not been entered as "becoming" does not appear in that line or in adjacent lines. Applicant is requested to verify where the amendment is to be made.

Applicant is reminded that the restriction requirement was vacated in the parent application 09/504538.

Applicant is also reminded that none of the papers submitted in the parent application are automatically of record in a child application, and must be separately submitted if to become of record..

Information Disclosure Statement

Reference CJ of paper #4 has not been considered. The citation is to a tome on internal medicine & specific pages for consideration were neither cited nor supplied.

Applicant is advised that should claims 1 and 9 be found allowable, claims 11 and 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 6-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating thyroid disorders using botulinum toxin by direct administration to the thyroid, does not reasonably provide enablement for a method which is administered by any route, in an unspecified amount and with an outcome whereby the method of determination is lacking . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). the issue of enablement in molecular biology was considered. There are eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. Although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable

It is suggested that the claims be amended to recite a therapeutically effective amount of the disclosed botulinum toxin, a manner of administration and a step to determine whether the desired outcome has been achieved. Although the art recognizes the use of botulinum toxin to block

release of neurotransmitters, the claims encompass administration in any location in unspecified amounts without direction . Since many embodiments would be expected to be non-operative, one of skill in the art has been given an invitation to experiment to determine an operative embodiment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
> regards as the invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "in an amount of between about". The word "about" renders the claim indefinite since it is a relative term that has not been defined in the specification. The metes and bounds of the claim are thus unclear. It is also unclear whether the dosage is in units/ kg body weight or some other parameter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by BIGLAN. The treatment of ocular retraction in a patients with Graves Disease with botulinum toxin is discussed. It is deemed anticipatory for the claimed subject matter because

Graves Disease is a is characterized as a hyperthyroid disease, with characteristic ocular retraction as a symptom.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.6319506. Although the conflicting claims are not identical, they are not patentably distinct from each other because the parathyroid is imbedded within the thyroid, and it is nearly impossible to avoid treating one without the other. Indeed the specification of each the patent and instant specification details treatment by injection of the cervical ganglia

Claims 1-7 and 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6328977. Although the conflicting claims are not identical, they are not patentably distinct from each other because the parathyroid is imbedded within the thyroid, and it is nearly impossible to avoid

treating one without the other. Indeed the specification of each the patent and instant specification details treatment by injection of the cervical ganglia

Claims 1-7 and 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6358513. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims is drawn to treatment of thyroid disorders by local administration of botulinum toxin..

Claims 1-7 and 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6524580. Although the conflicting claims are not identical, they are not patentably distinct from each other because each is drawn to treatment of thyroid disorders by administration of botulinum toxin.

Claims 1-7 and 9-12 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6524580. Although the conflicting claims are not identical, they are not patentably distinct from each other because each is drawn to treatment of thyroid disorders by administration of botulinum toxin.

Claims 1-7 and 9-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6585970. Although the conflicting claims are not identical, they are not patentably distinct from each other because each is drawn to treatment of thyroid disorders by administration of botulinum toxin.

Claims 1-7 and 9-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-7 and 10-12 of copending Application No. 09/706172. Although the conflicting claims are not identical, they

are not patentably distinct from each other because all claims of the instant application are to treatment with botulinum toxin, whereas the claims 1, 4 and 6-7 of the copending application. do not specify the neurotoxin. The claims of each application are of overlapping scope,

Claims 1-7 and 9-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-7 and 10-12 of copending Application No. 09/706215. Although the conflicting claims are not identical, they are not patentably distinct from each other because each is drawn to treatment of thyroid disorders by botulinum toxin.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

July 11, 2003